

WE CLAIM:

1. A process for preparing single rod-shaped or plate-like crystals of a glucagon-like peptide-1 related molecule (GLP) which comprises preparing a crystallization solution comprising a GLP, a buffering agent, an alcohol or a mono or disaccharide, and optionally, ammonium sulfate or zinc.

2. The process of Claim 1 wherein the GLP is at a final concentration of between about 1-10 mg/ml and is selected from the group consisting of a GLP-1 analog, a GLP-1 derivative, a dipeptidyl-peptidase-IV (DPP-IV) protected GLP, a GLP-1 peptide analog, or a biosynthetic GLP-1 analog, and wherein the buffering agent is about 10 to 50 mM, and about pH 6-7 and is selected from the group consisting of Tris, ammonium acetate, sodium acetate, or Bis-Tris, and wherein the alcohol or mono or disaccharide is selected from the group consisting of methanol, ethanol, propanol, glycerol, trehalose, mannitol, glucose, erythrose, ribose, galactose, fructose, maltose, sucrose, and lactose, and, optionally, wherein about 1% ammonium sulfate is present.

3. The process of Claim 1 wherein total zinc is in a 0.5-1.7 molar ratio to the GLP which is at a final concentration of between about 1-20 mg/ml and is selected from the group consisting of a GLP-1 analog, a GLP-1 derivative, a DPP-IV protected GLP, a GLP-1 peptide analog, or a biosynthetic GLP-1 analog, and wherein the buffering agent is about 10 to 100 mM, and about pH 7-10 and is selected from the group consisting of glycine, aspartic acid

or Tris, and wherein the alcohol or mono or disaccharide is selected from the group consisting of methanol, ethanol, propanol, glycerol, trehalose, mannitol, glucose, erythrose, ribose, galactose, fructose, maltose, sucrose, and lactose.

5

4. The process of **Claim 1** wherein the GLP is selected from the group consisting of a DPP-IV protected GLP, or a biosynthetic GLP.

10

5. The process of **Claim 1** wherein the GLP is a DPP-IV protected GLP selected from the group consisting of Val-8-GLP-1(7-37)OH, Thr-8-GLP-1(7-37)OH, Gly-8-GLP-1(7-37)OH, or Met-8-GLP-1(7-37)OH.

15

6. The process of **Claim 1** having the additional step of soaking the GLP crystals in a zinc containing solution.

20

7. GLP crystals having tetragonal flat rod shaped or plate-like morphology selected from the group consisting of a GLP-1 analog, a GLP-1 derivative, a DPP-IV protected GLP, a GLP-1 peptide analog, or a biosynthetic GLP-1 analog.

25

8. The crystals of **Claim 7** wherein the GLP is selected from the group consisting of DPP-IV protected GLP, or a biosynthetic GLP.

30

9. The crystals of **Claim 7** wherein the GLP is selected from the group consisting of Val-8-GLP-1(7-37)OH, Thr-8-GLP-1(7-37)OH, Gly-8-GLP-1(7-37)OH, or Met-8-GLP-1(7-37)OH.

10. GLP crystals whenever prepared by the process of **Claim 1**.

11. A substantially homogenous composition of GLP
5 crystals.

12. The composition of **Claim 11** wherein the GLP
crystals are selected from the group consisting of a GLP-1
analog, a GLP-1 derivative, a DPP-IV protected GLP, a GLP-1
10 peptide analog, or a biosynthetic GLP-1 analog.

13. The composition of **Claim 11** wherein the GLP is
selected from the group consisting of DPP-IV protected GLP,
or a biosynthetic GLP.

14. The composition of **Claim 11** wherein the GLP is
selected from the group consisting of Val-8-GLP-1(7-37)OH,
Thr-8-GLP-1(7-37)OH, Gly-8-GLP-1(7-37)OH, or Met-8-GLP-1(7-
37)OH.

15. A pharmaceutical formulation comprising a GLP
crystal as claimed in **Claim 7** together with one or more
pharmaceutically acceptable diluents, carriers or excipients
therefor.

16. A pharmaceutical formulation comprising a GLP
crystal as claimed in **Claim 8** together with one or more
pharmaceutically acceptable diluents, carriers or excipients
therefor.

17. A pharmaceutical formulation comprising a GLP crystal as claimed in **Claim 9** together with one or more pharmaceutically acceptable diluents, carriers or excipients therefor.

18. A pharmaceutical formulation comprising a GLP crystal as claimed in **Claim 10** together with one or more pharmaceutically acceptable diluents, carriers or excipients therefor.

19. The pharmaceutical formulation of **Claim 15** wherein the formulation is prepared by additions to and/or modifications of the post-crystallization mother liquor without separating the GLP crystals from the mother liquor.

20. The pharmaceutical formulation of **Claim 16** wherein the formulation is prepared by additions to and/or modifications of the post-crystallization mother liquor without separating the GLP crystals from the mother liquor.

21. The pharmaceutical formulation of **Claim 17** wherein the formulation is prepared by additions to and/or modifications of the post-crystallization mother liquor without separating the GLP crystals from the mother liquor.

22. The pharmaceutical formulation of **Claim 18** wherein the formulation is prepared by additions to and/or modifications of the post-crystallization mother liquor without separating the GLP crystals from the mother liquor.

-37-

23. A method of treating diabetes, obesity or related conditions in a mammal in need thereof, which comprises administering to said mammal a GLP crystal of **Claim 7**.

5 24. A method of treating diabetes, obesity or related conditions in a mammal in need thereof, which comprises administering to said mammal a composition of **Claim 11**.

10 25. A method of treating diabetes, obesity or related conditions in a mammal in need thereof, which comprises administering to said mammal a pharmaceutical formulation of **Claim 15**.

80727 66250250

add B1

add F2